IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

SMITH & NEPHEW, INC.	)	
	)	
Plaintiff,	)	
	)	**No. _____**
v.	)	
	)	**JURY TRIAL REQUESTED**
INTERLACE MEDICAL, INC.	)	
	)	
	)	
Defendant.	)	

COMPLAINT AND JURY DEMAND

Plaintiff Smith & Nephew, Inc. ("Smith & Nephew") by and through counsel, for its Complaint against Defendant Interlace Medical, Inc. ("Interlace") states and alleges as follows:

THE PARTIES AND JURISDICTION

1. This is a patent infringement action to stop Interlace's infringement of U.S. Patent No. 7,226,459, styled "Reciprocating Rotary Arthroscopic Surgical Instrument" (the " '459 Patent"). Smith & Nephew seeks entry of preliminary and permanent injunctive relief prohibiting Interlace from making, using, offering for sale, and/or selling devices infringing the '459 Patent, including the MyoSure Tissue Removal Device, as well as an award of monetary damages to compensate it for Interlace's willful infringement of the '459 Patent.

2. Smith & Nephew is a corporation existing and organized under the laws of the State of Delaware, with its principal place of business in Memphis, Tennessee and maintains a place of business at 150 Minuteman Road, Andover, Massachusetts 01810. Smith & Nephew is an industry leader in the design and manufacture of surgical instruments for cutting and removing tissue, including fibroid and polyp resection.

3. On information and belief, Interlace is a corporation existing and organized under the laws of the State of Delaware, with a principal place of business at 135 Newbury Street Framingham, Massachusetts 01701.

4. This action for patent infringement arises under the Patent Laws of the United States, in particular 35 U.S.C. § 271, 281, 283, 284, and 285. Subject matter jurisdiction is conferred upon this Court by 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Interlace, and venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400.

BACKGROUND

6. This case involves technology used to efficiently remove tissue, including semi-rigid tissue, in a surgical procedure. Smith & Nephew has invested significant time and resources in developing the medical device technology covered by many of its patents, including the ‘459 Patent, which protects, *inter alia*, the Dyonics Powermax Shaver Handpiece (the “Powermax”).

7. Historically, many conventional arthroscopic surgical instruments have had difficulty cutting semi-rigid tissue, insofar as the instruments maintained a tendency to bounce away from the tissue on contact. Other arthroscopic surgical instruments proved capable of initiating a cut into tissue, but possessed other limitations which became apparent when cutting large volumes of semi-rigid tissue, such as meniscus or intrauterine fibroid tissue.

8. The surgical instrument disclosed in the ‘459 Patent includes a drive coupled to a cutting member which causes simultaneous rotation, translation, and reciprocation of the cutting member in response to only a rotational force applied to the drive in a single direction. The simultaneous rotating and reciprocating member overcame the difficulties present in the prior art,

insofar as it limited the tendency of the instrument to bounce away from the tissue and provides a higher resection rate to shorten procedure length during procedures such as fibroid and polyp resection.

9. On information and belief, Interlace was founded in late 2006. Its Chief Technology Officer, Ronald Adams ("Adams"), joined Interlace at or around the time Interlace was founded.

10. Adams was formerly employed by Smith & Nephew from 2002-2006. While at Smith & Nephew, Adams was in the business unit which oversaw the development and commercialization of technology such as that embodied in the '459 Patent. At various times during his employment at Smith & Nephew, Adams was integrally involved with all aspects of the Operative Hysteroscopy System business, including research, product development, marketing and sale of products and devices such as the Powermax.

11. On information and belief, Interlace began focusing on developing technology which could compete with Smith & Nephew's Operative Hysteroscopy System business, including the Powermax device when Adams joined Interlace as its Chief Technology Officer.

12. In October 2009, Interlace announced that it had received 510K clearance from the U.S. Food and Drug Administration to market the MyoSure Hysteroscopic Tissue Removal System, including the MyoSure Tissue Removal Device. On information and belief, Interlace has also completed a multi-center clinical trial of the MyoSure Hysteroscopic Tissue Removal System. The system is touted as providing a safe, effective and fast way of removing fibroids and polyps, and Interlace promotes the fact that the blade "simultaneously rotates and reciprocates, which enables fast tissue cutting." See Exhibit 1 attached hereto.

COUNT I
PATENT INFRINGEMENT OF U.S. PATENT NO. 7,226,459

13. Smith & Nephew repeats and incorporates by reference the allegations in Paragraphs 1-12 as if fully set forth herein.

14. On October 26, 2001, U.S. Patent Application No. 09/983,810 ("the '810 application"), titled "Reciprocating Rotary Arthroscopic Surgical Instrument," was filed with the U.S. Patent and Trademark Office, naming as inventors Peter M. Cesarini, Karen Drucker, Rafal Jezierski, and Roger R. Cassidy, Jr. On June 5, 2007, the U.S. Patent and Trademark Office duly and legally issued the '810 application as the '459 Patent. The '459 Patent is attached as Exhibit 2.

15. Smith & Nephew is the sole and exclusive assignee and owner of the '459 patent by virtue of assignments that have been duly and properly recorded by the U.S. Patent and Trademark Office in its official files.

16. Interlace infringes the '459 Patent, literally and/or under the doctrine of equivalents, including at least claims 1, 25, 27, and 32, by making, using, selling, and/or offering for sale the MyoSure Tissue Removal Device ("Interlace Device") as part of the MyoSure Hysteroscopic Tissue Removal System, without permission or license from Smith & Nephew.

17. Claim 32 of the '459 Patent discloses:

> A surgical implement, comprising:
>
> a cutting member including an implement for cutting tissue;
>
> a drive coupled to the cutting member to simultaneously rotate, translate, and reciprocate the cutting member in response to only a rotational force applied to the drive in a single direction and to cut tissue during simultaneous rotation and translation of the cutting member; and
>
> an outer tubular member, the cutting member being received within the outer tubular member, the outer tubular member

> including a cutting window disposed proximate to a tip of the outer tubular member.

18. The Interlace Device includes a cutting member with an implement for cutting tissue; a drive coupled to the cutting member to (i) simultaneously rotate, translate, and reciprocate the cutting member in response to only a rotational force applied to the drive in a single direction, and (ii) cut tissue during simultaneous rotation and translation of the cutting member; and an outer tubular member including a cutting window proximately located to its tip which receives the cutting member.

19. Claim 1 of the ‘459 Patent discloses:

> A surgical instrument, comprising:
>
> a cutting member including an implement for cutting tissue; and
>
> a drive coupled to the cutting member to simultaneously rotate, translate, and reciprocate the cutting member in response to only a rotational force applied to the drive in a single direction and to cut tissue during simultaneous rotation and translation of the cutting member;
>
> wherein the drive member including a helical groove, and the drive includes a translation piece disposed in the groove such that rotary driving of the drive member results in simultaneous reciprocation of the drive member relative to the translation piece.

20. The Interlace Device includes a cutting member with an implement for cutting tissue; a drive coupled to the cutting member to (i) simultaneously rotate, translate, and reciprocate the cutting member in response to only a rotational force applied to the drive in a single direction, and (ii) cut tissue during simultaneous rotation and translation of the cutting member; and the drive includes a driver member attached to the cutting member, including a helical groove and a translation piece disposed in the helical groove such that rotary driving of the drive member results in simultaneous reciprocation of the drive member relative to the translation piece.

21. Claim 25 of the ‘459 Patent discloses:

> A surgical instrument, comprising:
>
> a cutting member including an implement for cutting tissue; and
>
> a drive coupled to the cutting member to simultaneously rotate, translate, and reciprocate the cutting member in response to only a rotational force applied to the drive in a single direction and to cut tissue during simultaneous rotation and translation of the cutting member;
>
> wherein the drive includes a drive member attached to the cutting member, the drive member including a helical groove, and the drive includes an inner drive hub coupled to the drive member such that the drive member rotates with the inner drive hub while being free to translate relative to the inner drive hub.

22. The Interlace Device includes a cutting member with an implement for cutting tissue; a drive coupled to the cutting member to (i) simultaneously rotate, translate, and reciprocate the cutting member in response to only a rotational force applied to the drive in a single direction, and (ii) cut tissue during simultaneous rotation and translation of the cutting member; and the drive includes a driver member attached to the cutting member, including a helical groove, and an inner drive hub coupled to the drive member such that the drive member rotates with the inner drive hub while being free to translate relative to the inner drive hub.

23. Claim 27 of the ‘459 Patent discloses:

> A surgical instrument, comprising:
>
> a cutting member including an implement for cutting tissue; and
>
> a drive coupled to the cutting member to simultaneously rotate, translate, and reciprocate the cutting member in response to only a rotational force applied to the drive in a single direction and to cut tissue during simultaneous rotation and translation of the cutting member;
>
> wherein the drive includes a drive member including a helical groove having a left-hand threaded helical channel.

24. The Interlace Device includes a cutting member with an implement for cutting tissue; a drive coupled to the cutting member to (i) simultaneously rotate, translate, and

reciprocate the cutting member in response to only a rotational force applied to the drive in a single direction, and (ii) cut tissue during simultaneous rotation and translation of the cutting member; and the drive includes a drive member including a helical groove having a left-hand threaded helical channel.

25. Smith & Nephew consistently and continuously marks patented articles covered by the ‘459 Patent, including the Powermax.

26. Interlace’s infringement of the ‘459 Patent is willful and deliberate, in light of (i) Smith & Nephew’s historical practice of marking its products, and (ii) Interlace’s prior knowledge of the ‘459 Patent, and Smith & Nephew’s Operative Hysteroscopy System business including the Powermax device, specifically through the intimate knowledge of Interlace’s CTO, Ron Adams, which he gained during his prior employment with Smith & Nephew. That Interlace is well aware of the scope of the ‘459 Patent is evident insofar as Interlace has identified the ‘459 Patent in several invention disclosure statements filed in conjunction with its own patent applications pending before the U.S. Patent and Trademark Office. Despite this knowledge, Interlace continues to make, offer for sale, and/or sell the Interlace Devices, often in direct competition with Smith & Nephew’s patented articles, including the Powermax.

27. Smith & Nephew is entitled to recover damages as a result of Interlace’s infringement of the ‘459 Patent, including lost profits and in no event less than a reasonable royalty, together with interest and costs. Smith & Nephew is also entitled to treble damages and recovery of attorney’s fees as a result of Interlace’s willful infringement of the ‘459 Patent.

21. Interlace’s continued infringement of the ‘459 Patent will also cause Smith & Nephew irreparable harm for which there is no adequate legal remedy, and Smith & Nephew should accordingly be granted preliminary and permanent injunctive relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Smith & Nephew prays for judgment that:

(a) Interlace infringes U.S. Patent No. 7,226,459 either literally or, in the alternative, under the doctrine of equivalents;

(b) Interface, Interface's respective officers, agents, servants, employees, contractors, and attorneys; and all those in active concert and participation with the foregoing persons and entities be enjoined temporarily, preliminarily, and permanently from further infringement of the '459 Patent;

(c) Smith & Nephew be awarded damages, together with prejudgment interest and costs, to compensate Smith & Nephew for the infringement by Interlace of the '459 Patent in accordance with 35 U.S.C. § 284, and that such award be increased by three times the amount found or assessed in accordance with 35 U.S.C. § 284 in light of Interlace's willful and knowing infringement;

(d) Smith & Nephew be awarded its costs, disbursements, and attorneys' fees pursuant to 35 U.S.C. § 285;

(e) Smith & Nephew recover pre-judgment interest on the amount awarded and post-judgment interest until paid, to the maximum extent allowed by law; and

(f) Smith & Nephew be awarded such other and further relief, at law or in equity, as the Court may deem just and proper.

JURY TRIAL DEMANDED

Smith & Nephew demands a jury trial of all issues so triable.

Dated: June 9, 2010

Respectfully Submitted,

Smith & Nephew, Inc.

By Its Attorneys

/s/ Maia H. Harris
Joseph J. Leghorn, BBO #292440
Maia H. Harris, BBO # 648208
NIXON PEABODY LLP
100 Summer Street
Boston, Massachusetts 02110-2131
(617) 345-1000
(617) 345-1300 (Facsimile)